

DETAILED ACTION

The receipt is acknowledged of applicants' "Appeal Brief" filed 04/09/2008.

Appeal conference was held on June 05, 2008, and the SPE panel decided the claims are allowable over the prior art of record, subjected to litigation search. The litigation search results showed no litigation found.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Michael Rubin on June 18, 2008.

The application has been amended as follows:

- 1) Claims 57, 68, 73, 82 and 95 have been canceled.

- 2) In claim 58, the phrase "controlled delivery device" bridging the first and second lines of the claims has been changed to ---- implantable convective delivery system----.
- 3) In claim 83, the phrase "controlled delivery device" bridging the first and second lines of the claims has been changed to ---- implantable convective delivery system----.
- 4) In claim 58, first line, the phrase "of claim 57" has been changed to ---- of claim 49----.
- 5) In claim 58, first line, the repeated phrase "of claim" between the word "method" and the phrase "of claim 57" has been deleted.
- 6) In claim 83, first line, the phrase "of claim 82" has been changed to ---- of claim 74----.
- 7) In claim 83, first line, the repeated phrase "of claim 82" between the word "method" and the phrase "of claim" has been deleted.

Allowable Subject Matter

2. The following is an examiner's statement of reasons for allowance: the present claims are directed to method of providing analgesia by delivering composition comprising fentanyl or fentanyl congener using implantable convective delivery system to deliver the drug for 48 hour or more at a low volume rate of 2ml/day or less and is sufficient to deliver analgesia in a subject. The closest prior art "Magruder" teaches

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implantable osmotic device to deliver active agent for long period of time, however, does not teach the specific analgesic any volume delivery rate or any period of time. Nelson teaches fentanyl in erodible implantable matrix to deliver fentanyl and not implantable convective device nor the low volume rate of delivery. Therefore Nelson and Magruder in combination do not teach the recited low volume delivery rate of fentanyl and its congener for long periods. Applicants disclosed that higher volume delivery rate provided several major disadvantages and render long term therapy is impractical.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Claims 48-56, 58-67, 69-72, 74-81, 83-94, 96-99 allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611